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Dedicated to the Restoration of Sight since 1961

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November 19, 1999

Jane Henney, M.D.
Commissioner
The Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 97N-484S; Request for extension of the Comment Period for the Proposed Rule Regarding the FDA's Proposed Approach to the Regulation of Suitability Determination for Donors of Human Cellular and Tissue-Based Products (21 CFR Parts 210, 211, 820, and 1271; 64 Federal Register, 18933 September 30, 1999).

Dear Commissioner Henney:

The Eye Bank Association of America (EBAA) respectfully requests an extension of the comment period for the Notice of Proposed Rulemaking published by the Food and Drug Administration (FDA) as Docket No. 97N-484S in the September 30, 1999 Federal Register regarding the FDA's Proposed Approach to the Regulation of Suitability Determination for Donors of Human Cellular and Tissue-Based Products. The Association represents over 100 member eye bank organizations, 99% of the entire U.S. eye banking community. All member eye banks are 501 (c) (3) organizations whose mission is to procure and provide donated human eye tissue for sight restoring transplantation procedures. Eye banks have a direct interest in the outcome of this proposed rule as it impacts on day-to-day practice which determines the suitability of eye tissue for transplantation procedures.

The EBAA is the oldest transplantation organization, founded in 1961 by the American Academy of Ophthalmology, and the first to establish medical standards; a comprehensive education and certification program for technicians and other eye bank professionals; continuing education for ophthalmologists and researchers and an institutionalized program for accreditation of eye banks. EBAA medical standards and its certification process have been used as models for other organizations. The Association takes pride in its record of safety and efficacy and strives to ensure the highest quality standards for the eye banking community.

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The EBAA believes that additional **time** is **necessary** to provide meaningful comments on the Proposed Rule **within the allotted** comment period ending December 29, 1999. We appeal to **you** for a GO-day extension of the **comment** period for the following reasons:

(1) Our initial **analysis** of the proposed rule raises some concern regarding the provisions relating to transmissible **spongiform encephalopathies (TSE)** and **Cruetzfeldt-Jakob Disease (CJD)**. **Specifically**, at the **EBAA Medical Advisory Board** meeting on October 22nd, the Board **delayed** implementation of an **EBAA** standard passed in June 1999 concerning a mandatory interview to screen for prion disease **until** a panel of independent **scientific** experts could **provide** appropriate guidelines and parameters **for** implementation. An ad hoc group of experts has been **assembled** and is conducting **an** in depth analysis of the issue and **its application to eye** banking. We would like the opportunity to **complete** collection of our scientific data on this subject and have it be considered for formulation of the final rule.

(2) As you are aware, the Department of **Health and Human Services** also Published a proposed rule proposing Standards **for** Privacy of Individually Identifiable Health Information on October 29, 1999 (Federal **Register**, 45 CFR 212, Parts 160-164, **November 3, 1999**). Public comments for this proposed rule are due January **3, 2000**. The **EBAA** believes careful analysis of this rule is **necessary** to protect health information **collected** from donors, donor **families**, and researchers. We would **like the** opportunity to **evaluate both** proposed rules in order to **respond** with consistency.

We appreciate your **willingness** to consider **this appeal** and **hope** additional time for response is granted. We **believe it is in the best interest** of **all those** involved with sight restoration procedures, and will benefit transplant **recipients**.

Sincerely,



Patricia **Aiken-O'Neill**, Esq.
President/CEO



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